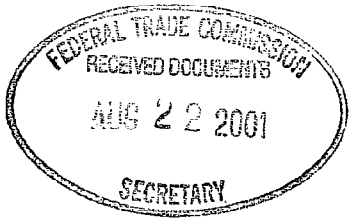

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	
Upsher-Smith Laboratories, Inc., a corporation,	)	**Docket No. 9297**
	)	**PUBLIC**
and	)	
American Home Products Corporation, a corporation.	)	

UPSHER-SMITH'S OPPOSITION TO THE FDA'S MOTION TO QUASH SUBPOENA

Rule 3.36 of the Commission's Rules of Practice specifically authorizes the issuance of a subpoena *duces tecum* upon "governmental agencies other than the Commission," provided that there is a showing that the material sought is (1) "reasonable in scope," (2) "falls within the limits of discovery," and (3) "cannot reasonably be obtained by other means." 16 C.F.R. 3.36(b). The FDA has failed to show that Your Honor was wrong in authorizing the subpoena, and the FDA's motion to quash should be denied.

As to Rule 3.36(b)'s first requirement, the FDA does not dispute that the material sought is "reasonable in scope." This stands to reason. The subpoena's specification is limited to a narrowly defined, easily identifiable set of documents. Upsher-Smith believes these documents are kept in the ordinary course of the FDA's business and may be easily gathered.

As to Rule 3.36(b)'s second requirement, the FDA does not dispute that the material sought "falls within the limits of discovery." Again, this stands to reason. The information sought

will lead to discovery of information concerning the identity of would-be competitors whose market entry was allegedly blocked. The information sought in the subpoena is necessary to enable Upsher-Smith to conduct further discovery that will address the FTC's alleged relevant market (of "all potassium chloride supplements approved by the FDA . . ." (Complaint at ¶ 21)) and the alleged denial of entry to would-be competitors.

As to Rule 3.36(b)'s third requirement, the FDA appears to argue that the material sought can reasonably be obtained through the FDA's FOIA procedures. This argument is wrong, if not disingenuous. In the subpoena, Upsher-Smith seeks:

> A copy of each New Drug Application and Abbreviated New Drug Application submitted after January 1, 1995 on which the "Chemical/BioChemical/Blood Product Name" is identified as POTASSIUM CHLORIDE. (This subpoena *duces tecum* seeks the completed Application form (Form 356h or equivalent), but does not seek any attachments or other materials accompanying the Application.).

FDA Regulation 21 C.F.R. §314.430, entitled "Availability for public disclosure of data and information in [a new drug] application or abbreviated [new drug] application," forbids disclosure of this information sought in a FOIA request: "If the existence of an unapproved application or abbreviated application has not been publicly disclosed or acknowledged, no data or information in the application or abbreviated application is available for public disclosure." 21 C.F.R. §314.430(c). Consequently, a FOIA request for the information specified is pre-

ordained to fail, and is an exercise in futility.[1]

The FDA's reliance on Your Honor's ruling in *Hoechst/Andrx* (FTC Docket No. 9293) is misapplied because the two cases and the corresponding subpoenas served on the FDA are substantially different. First, the documents sought by the subpoenas in the *Hoechst/Andrx* matter were not expressly excluded from FOIA. The information sought in *Hoechst/Andrx* consisted of a wide range of documents, including rulemaking notes and records held by FDA employees. Here, in contrast, FDA regulations expressly foreclose disclosure under FOIA.

Second, the FTC's complaint in *Hoechst/Andrx* did not expressly implicate FDA in its product market allegation. (See *Hoechst/Andrx* Complaint at ¶ 12, attached as exhibit E). The FTC has expressly implicated the FDA in its Complaint in this matter because the alleged product market places the FDA as the sole gatekeeper governing entry into the market. (See Complaint at ¶ 21, attached as exhibit D.) This makes the FDA a necessary party from which to seek discovery because potential entrants to the market are known only to the FDA. This was not the case in the *Hoechst/Andrx* matter.

Lastly, some of the information sought in the *Hoechst/Andrx* subpoenas did not comport to FTC Rule 3.36, particularly because some material could be sought from other sources. For example, the subpoenas requested records of FDA correspondence with certain known companies which was available through discovery issued to the companies themselves. To the contrary, the

[1] It should be noted that FDA regulations provide that, "within 10 working days...after a request for records is logged in...a letter shall be sent to the persons making the request determining whether, or the extent which, the agency will comply with the request, and if any records are denied, the reasons therefore." 21 C.F.R. §20.41(b). The FDA has not complied with this regulation. As discussed above, Upsher-Smith has received a letter from the FDA promising "to respond" to the request "as soon as possible." However, Upsher-Smith has not received a letter determining whether the agency will comply with the request.

FDA is the only identifiable source of the NDA and ANDA forms Upsher-Smith seeks.

Notably, the FDA advances no other argument in their Motion other than the one based on the FOIA procedures. Rule 3.34(c) states: "Such motions [to quash] shall set forth all all assertions of privilege or other factual or legal objections to the subpoena, including all appropriate arguments, affidavits and other supporting documents . . . ." Thus, the FDA has waived any other privileges or factual or legal objections to the subpoena.

In short, Upsher-Smith's subpoena *duces tecum* seeks information that is available only through subpoenaing the FDA. Upsher-Smith does not know if any non-public NDA or ANDA filings exist, let alone who may have filed them. Moreover, this information is directly applicable to the allegations in the FTC's complaint, and necessary for Upsher-Smith to conduct full discovery in response to the allegations.

CONCLUSION

For the reasons stated above, the FDA's Motion to Quash should be denied, and Upsher-Smith's subpoena *duces tecum* served upon the FDA should be enforced.

Dated: August 22, 2001

Respectfully submitted,

WHITE & CASE LLP

By: _____

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601 Thirteenth Street, N.W.
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Facsimile: (202) 639-9355

Attorneys for Upsher-Smith Laboratories, Inc.

CERTIFICATE OF SERVICE

I, Sanjiv S. Kala, hereby certify that on August 22, 2001, I caused a copy of Upsher-Smith's Opposition To the FDA's Motion to Quash Subpoena to be served upon the following persons by courier delivery.

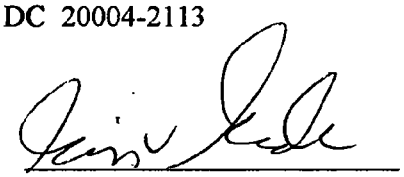
The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Carl I Turner
Associate Chief Counsel
U.S. Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

Karen G. Bokat
Federal Trade Commission, 3115
601 Pennsylvania Avenue, N.W.
Washington, DC 20580

Laura S. Shores
Howrey Simon Arnold & White
1299 Pennsylvania Avenue, N.W.
Washington, DC 20004

Cathy Hoffman
Arnold & Porter
Thurman Arnold Building
555 Twelfth Street, N.W.
Washington, DC 20004-2113



Sanjiv S. Kala

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	
Upsher-Smith Laboratories, Inc., a corporation,	)	**Docket No. 9297**
	)	**PUBLIC**
and	)	
American Home Products Corporation, a corporation.	)	

UPSHER-SMITH'S MOTION FOR AN ORDER AUTHORIZING THE SECRETARY OF THE COMMISSION TO ISSUE A SUBPOENA *DUCES TECUM* TO THE FOOD AND DRUG ADMINISTRATION

Pursuant to Rule 3.36 of the Commission's Rules of Practice, Upsher-Smith hereby moves for an Order authorizing the Secretary of the Commission to issue a subpoena *duces tecum* to the Food and Drug Administration. The accompanying memorandum attaches a description of the material to be produced pursuant to the proposed subpoena. Complaint Counsel does not oppose this motion.

Dated: July 25, 2001

Respectfully submitted,

WHITE & CASE LLP

By: _____

Robert D. Paul
J. Mark Gidley
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Telephone: (202) 626-3600
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Attorneys for Upsher-Smith Laboratories, Inc.

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	
Upsher-Smith Laboratories, Inc., a corporation,	)	**Docket No. 9297**
and	)	**PUBLIC**
American Home Products Corporation, a corporation.	)	

UPSHER-SMITH'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR AN ORDER AUTHORIZING THE SECRETARY OF THE COMMISSION TO ISSUE A SUBPOENA *DUCES TECUM* TO THE FOOD AND DRUG ADMINISTRATION

As explained below, Upsher-Smith seeks to serve a narrowly focused subpoena *duces tecum* on the Food and Drug Administration to discover certain facts critical to Upsher-Smith's defense of this proceeding. Complaint Counsel does not oppose this motion.

BACKGROUND

The Commission's Complaint alleges that entry has been restricted for the manufacture and sale of all potassium chloride supplements, and that the FDA's grant of 180-day exclusivity to Upsher-Smith has blocked entry of other versions K-Dur 20. (Complaint ¶¶ 21, 28, 29 47, 50, 63). In support of these allegations, the Complaint identifies only one company that has filed an ANDA for a generic version of K-Dur 20. That company is Andrx, whose ANDA evidently has not been tentatively approved by the FDA. (Complaint ¶ 61). In order to fully respond to the Complaint's allegations, Upsher-Smith seeks to discover exactly which, if any, other companies

have applied to the FDA for NDAs and ANDAs to market generic versions of K-Dur 20 or similar products. Because the identity of NDA and ANDA filers is kept confidential by the FDA until the applications are approved or tentatively approved, a subpoena *duces tecum* is necessary to obtain this information. Accordingly, Upsher-Smith seeks such a subpoena requiring the FDA to produce documents sufficient to identify the NDA and ANDA filers. Upsher-Smith will then seek to discover from the alleged filers themselves whether or not they have actually been blocked from competing by the FDA's grant of 180-day exclusivity to Upsher-Smith.

ARGUMENT

I. The Requested Subpoena *Duces Tecum* Because Satisfies All Requirements Under the Applicable Commission Rules of Practice.

Rule 3.36(b) of the Commission's Rules of Practice requires that a party seeking issuance of a subpoena for records of governmental agencies make a specific showing that:

> "(1) The material sought is reasonable in scope;
>
> (2) If for the purposes of discovery, the material falls within the limits of discovery under §3.31(c)(1), or, if an adjudicative hearing, the material is reasonably relevant;
>
> (3) The information or material sought cannot reasonably be obtained by other means; and
>
> (4) With respect to subpoenas to be served in a foreign country, the party seeking discovery has a good faith believe that the discovery requested would be permitted by treaty, law, custom or practice in the country from which the discovery is sought and that any additional procedural requirements have been or will be met before the subpoena is served."

16 C.F.R. § 3.36(b). If these requirements are satisfied, the Court may authorize the Secretary of the Commission to issue the requested subpoena *duces tecum* under Rule 3.31.

A. **The Material Sought In This Motion Is Reasonable in Scope.**

Upsher-Smith seeks only copies of the forms submitted to the FDA by NDA and ANDA filers for potassium chloride since 1995. (See Attachment A). This two-page form contains basic company identification data and information about the drug for which the company is seeking FDA approval. (See Exhibit B, Form FDA 356h). While many NDA and ANDA filings are accompanied by volumes of attachments necessary for the FDA's review of testing results, Upsher-Smith seeks only copies of Form FDA 356h and not the attachments.

Upsher-Smith does not believe that the subpoena would be burdensome to the FDA. Indeed, Upsher-Smith believes that the information concerning NDA and ANDA filers of potassium chloride products is readily available and kept by the FDA as information accessible during the ordinary course of business.

Given the importance of this information to this matter, the relative burden on the FDA is minimal. The specification in the subpoena is for a limited set of material, the volume of which is expected to be relatively small and kept in the ordinary course of business. Moreover, the information supplied by the FDA is expected to lead to the discovery of additional information critical to the prompt and efficient resolution of this adjudicative proceeding. Again, Upsher-Smith only seeks minimal, but essential, information contained in the responsive NDA and ANDA files in an effort to reduce the burden imposed on the FDA

B. **The Material Sought Falls Within the Limits of Discovery.**

Rule 3.31(c)(1), which addresses the general rules and limitations on the scope of discovery, states in pertinent part :

> "Parties may obtain discovery to the extent that it may be reasonably expected to yield information relevant to the allegations of the complaint, to the proposed relief, or to the defenses of any respondent."

16 C.F.R. 3.31(c)(1).

To respond fully to the Complaint's allegations, Upsher-Smith needs information from the FDA on exactly who has sought to compete in the manufacture and sale of potassium chloride supplements during all relevant times. Upsher-Smith needs copies of NDA and ANDA forms to identify who may have evidence that other companies were not barred from entering the market. Once the NDA and ANDA filers have been identified, Upsher-Smith anticipates serving additional subpoenas on the filers. Accordingly, Upsher-Smith expects that information obtained from the FDA subpoena will clarify the condition of the potassium chloride market and specifically address the allegations that competitors were barred from entry.

C. **The Material Sought Cannot Be Obtained By Other Means.**

The FDA does not publicly disclose the identity of NDA and ANDA filers until the FDA tentatively or finally approves their applications. Because the FDA keeps this material confidential, a subpoena is necessary to obtain the filers' identities.[1]

Other than serving a subpoena upon the FDA, Upsher-Smith's only alternative to obtain this information is to guess, and accordingly serve subpoenas on the more than 150 known pharmaceutical companies that do business in the United States to determine if any had made a potassium chloride NDA or ANDA filing with the FDA since 1995. This exercise obviously

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[1] Upsher-Smith cannot obtain this information from respondent Schering-Plough. The Complaint alleges that the relevant product markets include the "manufacture and sale of all potassium chloride supplements approved by the FDA." (Complaint ¶ 21). Schering-Plough would only receive Paragraph IV notification from ANDA filers seeking to replicate its specific patented forms of potassium chloride. However, because the Complaint alleges a relevant market broader than the specific Schering-Plough patents, only the FDA has information about all NDA and ANDA filers for the alleged relevant markets.

would impose an enormous cost of time and money on Upsher-Smith and the parties subpoenaed. Moreover, such a method of discovery would not yield a certain result because there is a probability that some potential potassium chloride NDA and ANDA filers would still be unidentified. Consequently, this proposed FDA subpoena is the fastest, most efficient method for Upsher-Smith to locate the complete set of potential market competitors.

While the FDA naturally has an interest in ensuring that the identity of NDA and ANDA filers remain confidential, any concern about maintaining confidentiality is alleviated by the provisions of the Protective Order entered in this case. As the terms of the Protective Order indicate, the FDA need only clearly mark the documents as "Restricted Confidential, Attorney Eyes Only" to ensure that the information will continue to be treated confidentially. (Protective Order Governing Discovery Material, p. 6).

D. Because This Subpoena Does Not Involve Service In Any Foreign State, Rule 3.36(b)(4) Does Not Apply.

Because this subpoena does not involve service in a foreign jurisdiction, the Court does not need to consider any applicable treaty, law, custom or practice in the country from which the discovery is sought.

CONCLUSION

For the reasons stated above, the Court should grant Upsher-Smith's Motion and authorize the Secretary of the Commission to issue a subpoena *duces tecum* to the FDA.

Dated: July 25, 2001

Respectfully submitted,

WHITE & CASE LLP

By: _____

Robert D. Paul
J. Mark Gidley
Christopher M. Curran
Gustav P. Chiarello
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Washington, D.C. 20005-3807
Telephone: (202) 626-3600
Facsimile: (202) 639-9355

Attorneys for Upsher-Smith Laboratories, Inc.

MATERIAL TO BE PRODUCED

1. A copy of each New Drug Application and Abbreviated New Drug Application submitted after January 1, 1995 on which the "Chemical/BioChemical/Blood Product Name" is identified as POTASSIUM CHLORIDE. (This subpoena *duces tecum* seeks the completed Application form (Form 356h or equivalent), but does not seek any attachments or other materials accompanying the Application.)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: March 31, 2003
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
TELEPHONE NO. *(Include Area Code)*	FACSIMILE (FAX) Number *(Include Area Code)*
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):*	AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)*

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*	CODE NAME *(If any)*

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:

(PROPOSED) INDICATION(S) FOR USE:

APPLICATION INFORMATION

APPLICATION TYPE *(check one)* ☐ NEW DRUG APPLICATION (21 CFR 314.50) ☐ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☐ 505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug Holder of Approved Application

TYPE OF SUBMISSION *(check one)* ☐ ORIGINAL APPLICATION ☐ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT
☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION: _____

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION

PROPOSED MARKETING STATUS *(check one)* ☐ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED _____ THIS APPLICATION IS ☐ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

This application contains the following items: *(Check all that apply)*	
	1. Index
	2. Labeling *(check one)* ☐ Draft Labeling ☐ Final Printed Labeling
	3. Summary (21 CFR 314.50 (c))
	4. Chemistry section
	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
	15. Establishment description (21 CFR Part 600, if applicable)
	16. Debarment certification (FD&C Act 306 (k)(1))
	17. Field copy certification (21 CFR 314.50 (l)(3))
	18. User Fee Cover Sheet (Form FDA 3397)
	19. Financial Information (21 CFR Part 54)
	20. OTHER *(Specify)*

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act Section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
	( )

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
CBER, HFM-99
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
CDER, HFD-94
12420 Parklawn Dr., Room 3046
Rockville, MD 20852

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

FORM FDA 356h (4/00)

INSTRUCTIONS FOR FILLING OUT FORM FDA 356h

APPLICANT INFORMATION This section should include the name, street address, telephone and facsimile numbers of the legal person or entity submitting the application in the appropriate areas. Note that, in the case of biological products, this is the name of the legal entity or person to whom the license will be issued. The name, street address and telephone number of the legal person or entity authorized to represent a non-U.S. Applicant should be entered in the indicated area. Only one person should sign the form.

PRODUCT DESCRIPTION This section should include all of the information necessary to identify the product that is the subject of this submission. For new applications, the proposed indication should be given. For supplements to an approved application, please give the approved indications for use.

APPLICATION INFORMATION If this submission is an ANDA or 505(b)(2), this section should include the name of the approved drug that is the basis of the application and identify the holder of the approved application in the indicated areas.

TYPE OF SUBMISSION should be indicated by checking the appropriate box:

Original Application = a complete new application that has never before been submitted;

Amendment to a Pending Application = all submissions to pending original applications, or pending supplements to approved applications, including responses to Information Request Letters;

Resubmission = a complete response to an action letter, or submission of an application that has been the subject of a withdrawal or a refusal to file action;

Presubmission = information submitted prior to the submission of a complete new application;

Annual Report = periodic reports for licensed biological products (for NDAs Form FDA-2252 should be used as required in 21 CFR 314.81 (b)(2));

Establishment Description Supplement = supplements to the information contained in the Establishment Description section (#15) for biological products;

Efficacy Supplement = submissions for such changes as a new indication or dosage regimen for an approved product, a comparative efficacy claim naming another product, or a significant alteration in the patient population; e.g., prescription to Over-The-Counter switch;

Labeling Supplement = all label change supplements required under 21 CFR 314.70 and 21 CFR 601.12 that do not qualify as efficacy supplements;

Chemistry, Manufacturing and Controls Supplement = manufacturing change supplement submissions as provided in 21 CFR 314.70, 21 CFR 314.71, 21 CFR 314.72 and 21 CFR 601.12;

Other = any submission that does not fit in one of the other categories (e.g., Phase IV response). If this box is checked the type of submission can be explained in the **REASON FOR SUBMISSION** block.

Submission of Partial Application Letter date of agreement to partial submission should be provided. Also, provide copy of scheduled plan.

CBE "Supplement-Changes Being Effected" supplement submission for certain moderate changes for which distribution can occur when FDA receives the supplement as provided in 21 CFR 314.70 and 21 CFR 601.12.

CBE-30 "Supplement-Changes Being Effected in 30 Days" supplement submission for certain moderate changes for which FDA receives at least 30 days before the distribution of the product made using the change as provided in 21 CFR 314.70 and 21 CFR 601.12.

Prior Approval (PA) "Prior Approval Supplements" supplement submission for a major change for which distribution of the product made using the change cannot occur prior to FDA approval as provided in 21 CFR 314.70 and 21 CFR 601.12.

REASON FOR SUBMISSION This section should contain a brief explanation of the submission, e.g., "manufacturing change from roller bottle to cell factory" or "response to Information Request Letter of 1/9/97" or "Pediatric exclusivity determination request" or "to satisfy a subpart H postmarketing commitment".

NUMBER OF VOLUMES SUBMITTED Please enter the number of volumes, including and identifying electronic media, contained in the archival copy of this submission.

This application is
☐ Paper ☐ Paper and Electronic ☐ Electronic
Please check the appropriate box to indicate whether this submission contains only paper, both paper and electronic media, or only electronic media.

ESTABLISHMENT INFORMATION This section should include information on the locations of all manufacturing, packaging and control sites for both drug substance and drug product. If continuation sheets are used, please indicate where in the submission they may be found. For each site please include the name, address, telephone number, registration number (Central File Number), Drug Master File number, and the name of a contact at the site. The manufacturing steps and/or type of testing (e.g. final dosage form, stability testing) conducted at the site should also be included. Please indicate whether the site is ready for inspection or, if not, when it will be ready. Please note that, when applicable, the complete establishment description is requested under item 15.

CROSS REFERENCES This section should contain a list of all License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs and DMFs that are referenced in the current application.

Items 1 through 20 on the reverse side of the form constitute a check list that should be used to indicate the types of information contained within a particular submission. Please check all that apply. The numbering of the items on the checklist is not intended to specify a particular order for the inclusion of those sections into the submission. The applicant may include sections in any order, but the location of those sections within the submission should be clearly indicated in the Index. It is therefore recommended that, particularly for large submissions, the Index immediately follows the Form FDA 356h and, if applicable, the User Fee Cover Sheet (Form FDA 3397).

The CFR references are provided for most items in order to indicate what type of information should be submitted in each section. For further information, the applicant may consult the guidance documents that are available from the Agency.

Signature The form must be signed and dated. Ordinarily only one person should sign the form, i.e., the applicant, or the applicant's attorney, agent, or other authorized official. However, if the person signing the application does not reside or have a place of business within the United States, the application should be countersigned by an attorney, agent, or other authorized official who resides or maintains a place of business within the United States.

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	
Upsher-Smith Laboratories, Inc., a corporation,	)	**Docket No. 9297**
	)	**PUBLIC**
and	)	
American Home Products Corporation, a corporation.	)	

ORDER

Upon consideration of Upsher-Smith's Motion For An Order Authorizing The Secretary of the Commission To Issue A Subpoena *Duces Tecum* to the Food and Drug Administration and the record as a whole, it is hereby ORDERED that the Consent Motion is GRANTED. In accordance with Commission Rule 3.36(c), Upsher-Smith may forward to the Secretary a request, with this Order attached, for an authorized subpoena *duces tecum* to be served on the United States Food and Drug Administration.

Dated: August ___, 2001
Washington, DC

D. Michael Chappell
Administrative Law Judge

CERTIFICATE OF SERVICE

I, J. Carlos Alarcon, hereby certify that on July 25, 2001, I caused a copy of Upsher-Smith Consent Motion For An Order Authorizing the Secretary of the Commission to Issue a Subpoena *Duces Tecum* To the United States Food and Drug Administration to be served upon the following persons by courier delivery.

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Karen G. Bokat
Federal Trade Commission, 3115
601 Pennsylvania Avenue, N.W.
Washington, DC 20580

Laura S. Shores
Howrey Simon Arnold & White
1299 Pennsylvania Avenue, N.W.
Washington, DC 20004

Cathy Hoffman
Arnold & Porter
Thurman Arnold Building
555 Twelfth Street, N.W.
Washington, DC 20004-2113

J. Carlos Alarcon

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FACSIMILE TRANSMISSION

Date:	August 8, 2001	**No. of Pages (including cover):**	3
To:	Freedom of Information Staff **Food and Drug Administration**	**Fax Number:** Contact Number:	301-443-1726 301827-6500
	Mr. Carl Turner, Esq. **Office of Chief Counsel, Food and Drug Administration**		301-443-0933 301827-1137
From:	Gustav P. Chiarello	**Reference No.:**	1205696-0002

Please See Attached FOIA Request.

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August 8, 2001

BY FACSIMILE

Freedom of Information Staff (HFI-35)
Food and Drug Administration
Room 12A-16
5600 Fishers Lane
Rockville, MD 20857

Re: Freedom of Information Act Request

To Whom It May Concern:

On behalf of Upsher-Smith Laboratories, Inc., I hereby submit a Freedom of Information Act ("FOIA") request to the Food and Drug Administration. I am seeking the following materials:

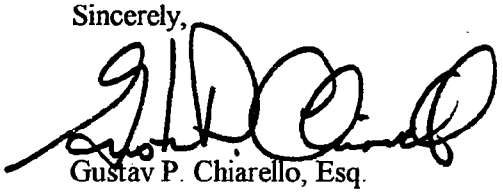
> One copy of each New Drug Application or Abbreviated New Drug Application (Form FDA 356h or equivalent) submitted to the Food and Drug Administration after January 1, 1995, on which the "Chemical/BioChemical/Blood Product Name" is identified as POTASSIUM CHLORIDE, and which were not or have not yet been approved by the FDA. (This FOIA request seeks a copy of the 2-page Form FDA 356h only, and does not seek any attachments or other materials accompanying the Application.)

To aid the Freedom of Information Staff, ANDA and NDA files are most likely maintained and accessible from the Center for Drug Evaluation and Research (CDER), HFD-94, 12420 Parklawn Dr., Room 3046, Rockville, MD 20852. Regarding costs of production, I expect that the cost of producing this information will be minimal, and will reimburse the FDA for any costs in production.

Please note that this request is not for commercial purposes, but rather to aid in discovery of information relevant to an ongoing administrative adjudication before the Federal Trade Commission.

Please arrange for delivery of the documents to my attention at the above listed address. Time is of the essence regarding this request, and your prompt response to this request is greatly appreciated. Please contact me directly (Tel. 202-626-3680) if you have any questions regarding this request.

Sincerely,



Gustav P. Chiarello, Esq.

cc: Mr. Carl Turner, Office of Chief Counsel,
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

WHITE & CASE
ATTN: G CHIARELLO
601 THIRTEENTH ST NW STE 600 S
WASHINGTON, DC 20005-3807

08/10/01

In reply refer to:
01014099

Dear Requester:

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

POTASSIUM CHLORIDE - NDA OR ANDA SBMTD
AFTER 1/1/95

We will respond as soon as possible and may charge you a fee for processing your request. If you have any questions about your request, please call us at 301-827-6563 or write to us at:

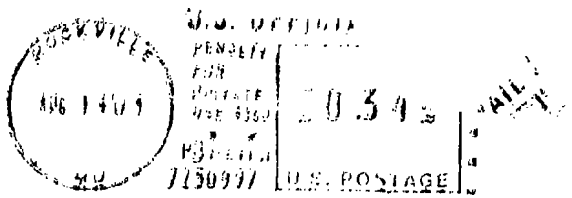
Food and Drug Administration
Division of Freedom of Information
5600 Fishers Lane, HFI-35
Rockville, MD 20857

If you call or write, use the reference number above which will help us to answer your questions more quickly.

DEPARTMENT OF
HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

Official Business
Penalty For Private Use $300



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UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	
Upsher-Smith Laboratories, a corporation,	)	Docket No. 9297
and	)	
American Home Products Corporation, a corporation.	)	

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in the agency by said Act, the Federal Trade Commission ("Commission"), having reason to believe that respondents Schering-Plough Corporation ("Schering"), Upsher-Smith Laboratories ("Upsher-Smith"), and American Home Products Corporation ("AHP") have engaged in conduct, as described herein, that violates Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows:

Nature of the Case

1. This action challenges unlawful agreements by Schering, Upsher-Smith, and AHP to delay the entry of low-cost generic competition to Schering's highly profitable prescription drug K-Dur 20, a product used to treat patients who suffer from insufficient levels of potassium, a condition that can lead to serious cardiac problems.

2. When confronted with the prospect of competition to K-Dur 20 through generic entry by Upsher-Smith and ESI Lederle, Incorporated ("ESI"), a division of AHP, Schering structured and entered into agreements with Upsher-Smith, AHP, and ESI that are

keeping Upsher-Smith, ESI, and all other potential generic competitors out of the market. These agreements have cost consumers in excess of $100 million.

The Respondents

3. Respondent Schering is a New Jersey corporation with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey. Schering is engaged in the discovery, development, and marketing of brand-name and generic drugs, as well as over-the-counter healthcare and animal care products. Schering's net sales for 1999 were approximately $9.2 billion.

4. Respondent Upsher-Smith is a Minnesota corporation with its principal place of business at 14905 23rd Avenue North, Plymouth, Minnesota. Upsher-Smith is engaged in the discovery, development, and marketing of drugs. Upsher-Smith markets twelve brand-name products, all of which are sold in the United States.

5. Respondent AHP is a Delaware corporation with its principal place of business at 5 Giralda Farms, Madison, New Jersey. AHP engages in the discovery, development, and marketing of brand-name and generic drugs, as well as over-the-counter medications. AHP had net sales of $13.5 billion in 1999.

6. ESI Lederle, Incorporated, a division of AHP, engages in the research, manufacture, and sale primarily of generic drugs.

7. Schering, Upsher-Smith, and AHP, at all relevant times herein, have been, and are now, corporations as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

8. Respondents' acts and practices, including the acts and practices alleged herein, are in or affect commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

Federal Regulation of Prescription Drugs

9. Under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., approval by the Food and Drug Administration ("FDA") is required before a company may market or sell a prescription drug in the United States.

10. Newly developed prescription drugs are often protected by patents and marketed under proprietary brand names. Such new drugs are referred to as "brand name drugs" or "branded drugs." FDA approval for a branded drug is generally sought by filing a New Drug Application ("NDA") with the FDA.

11. Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355 (the "Hatch-Waxman Act"), to facilitate entry of generic drugs while maintaining incentives for new drug development.

12. FDA approval for a generic drug is generally sought by filing an Abbreviated New Drug Application ("ANDA") with the FDA. The ANDA applicant has to demonstrate that the generic drug is bioequivalent to the brand name drug that it references.

13. When a brand name drug is protected by one or more patents, an ANDA applicant that intends to market its generic product prior to expiration of any patents may proceed to seek FDA approval, but must certify in the ANDA either that (1) the generic version does not infringe the patents on the brand name drug or (2) the patents are invalid. This is called a "Paragraph IV Certification."

14. The ANDA applicant must then notify the NDA holder and the patent holder of the filing of its ANDA. If, within 45 days of receiving such notification, a patent infringement suit is initiated against the ANDA applicant, the FDA must stay its final approval of the ANDA for the generic drug until the earliest of (1) the patent expiration, (2) a judicial determination of the patent litigation, or (3) the expiration of a 30-month waiting period.

15. The Hatch-Waxman Act gives the first firm filing an ANDA for a generic version of a brand name drug with a Paragraph IV Certification a period of protection from competition from other generic versions of the drug. The FDA may not approve other generic versions of the same drug until 180 days after the earlier of the date on which (1) the first firm begins commercial marketing of its generic version of the drug, or (2) a court finds the patents claiming the brand name drug are invalid or not infringed. This is referred to as "the 180-day Exclusivity Period."

16. If the first firm filing an ANDA loses its patent litigation with the patent holder, no firm is given a 180-day Exclusivity Period.

The Impact of Generic Competition

17. Generic entry generally leads to a significant erosion of the branded drug's market share and unit and dollar sales within the first year. As additional generic drugs enter, the price of the generic drugs typically decreases even further and the branded drug's market share erodes further.

18. Pharmacists generally are permitted, and in some instances required, to substitute generic drugs for their branded counterparts, unless the prescribing physician has directed that the branded product be dispensed.

19. Certain third-party payers of prescription drugs (e.g., managed care plans, Medicaid

programs) encourage or insist on the use of generic drugs in lieu of their branded counterparts wherever possible.

Relevant Product and Geographic Market

20. The relevant geographic market in which to evaluate the conduct of Schering, Upsher-Smith, and AHP is the United States.

21. The relevant product markets are the manufacture and sale of all potassium chloride supplements approved by the FDA, and narrower markets contained therein, including the manufacture and sale of 20 milliequivalent extended-release potassium chloride tablets and capsules.

22. Potassium chloride supplements are used to treat patients with depleted potassium levels, a condition that typically occurs when people take certain anti-hypertensive medications to lower blood pressure. Depleted potassium levels can cause dangerous cardiac problems.

23. Patients who suffer from depleted potassium levels have no practical substitute for potassium chloride supplements.

24. For clinical reasons, among others, physicians and patients prefer 20 milliequivalent extended-release potassium chloride tablets over other forms and dosages of potassium chloride.

25. The existence of other potassium chloride products has not significantly constrained Schering's pricing of K-Dur 20.

Market Power

26. Schering has approximately 69% of the sales of potassium chloride supplements.

27. Schering's K-Dur 20 has 100% of the sales of 20 milliequivalent extended-release potassium chloride tablets and capsules.

28. At all times relevant herein, entry into the relevant markets was restricted and unlikely to diminish Schering's market share. Before entry could occur, potential entrants were required to, *inter alia*, file an NDA or an ANDA with the FDA, and obtain FDA final approval. At all relevant times, only one NDA for a new potassium chloride supplement was pending before the FDA. That NDA, for a powder form, has not been approved; and, even if it were approved, because of the disadvantages of potassium chloride powders compared to tablets, a new potassium chloride powder would be unlikely to diminish Schering's market share. If a new NDA were to be filed with the FDA, final approval

would likely take a minimum of 12-18 months.

29. At all times relevant herein, FDA final approval of an ANDA for a generic version of K-Dur 20 for anyone other than Upsher-Smith was blocked. Pursuant to the Hatch-Waxman Act, Upsher-Smith was eligible for the right to a 180-day Exclusivity Period for the sale of a generic version of K-Dur 20. As a result, no company could obtain final FDA approval of an ANDA to market or sell a generic version of K-Dur 20 untill180 days after Upsher-Smith first sold its product, or until Upsher-Smith's exclusivity right is relinquished, forfeited or otherwise expired.

30. At all times relevant herein, the existence of generic versions of branded potassium chloride supplements other than K-Dur 20 has not constrained Schering's market power in the potassium chloride supplement market.

Background

31. Schering manufactures and markets two extended-release microencapsulated potassium chloride products: K-Dur 20 milliequivalent ("K-Dur 20") and K-Dur 10 milliequivalent ("K-Dur 10"). Both products are marketed as brand name drugs.

32. In 1998, sales of Schering's two K-Dur products were over $220 million.

33. Potassium chloride, the active ingredient in potassium chloride supplements, is not patentable.

34. Schering's K-Dur 20 and K-Dur 10 are covered by a formulation patent owned by Schering, patent number 4,863,743 (the "'743 patent"), which claims a controlled release potassium chloride tablet. The '743 patent expires on September 5, 2006.

35. The allegedly novel aspect of the'743 patent is the composition of the coating material applied to previously known potassium chloride crystals.

36. Schering anticipated generic entry prior to expiration of its '743 patent.

37. Prior to 1997, Schering projected that the first year of low-priced generic competition would reduce branded K-Dur 20's sales by over $30 million.

Schering/Upsher-Smith Agreement Not To Compete

38. On August 6, 1995, Upsher-Smith filed an ANDA with the FDA to market Klor Con M20, a generic version of Schering's K-Dur 20. Upsher-Smith's ANDA was the first for a generic version of K-Dur 20. Upsher-Smith submitted a Paragraph IV Certification with this ANDA and, on November 3, 1995, Upsher-Smith notified Schering of its Paragraph IV Certification and ANDA filing.

39. Schering sued Upsher-Smith for patent infringement in the United States District Court for the District of New Jersey on December 15, 1995, alleging that Upsher-Smith's Klor-Con M20 infringed Schering's '743 patent. This lawsuit triggered the statutory waiting period of up to 30 months for final FDA approval of the Upsher-Smith product.

40. This lawsuit was strongly contested by Upsher-Smith.

41. As the first ANDA filer with a Paragraph IV Certification for a generic version of Schering's K-Dur 20, Upsher-Smith is eligible for the 180-day Exclusivity Period.

42. Because Upsher-Smith is eligible for the 180-day Exclusivity Period, no other generic manufacturer can obtain final FDA approval to market a generic version of K-Dur 20 until after the exclusivity period has expired, whether or not the other marketer has a product that infringes the Schering patent.

43. During the first half of 1997, Upsher-Smith prepared to launch commercially Klor Con M20 no later than May 1998, the month in which the 30-month stay of FDA approval was to expire.

44. On June 17, 1997, on the eve of their patent trial, Schering and Upsher-Smith agreed to settle their litigation. Under the settlement, Schering agreed to make unconditional payments of $60 million to Upsher-Smith; Upsher-Smith agreed not to enter the market, either with the allegedly infringing generic version of K-Dur 20 or with any other generic version of K-Dur 20, regardless of whether such product would infringe Schering's patents, until September 2001; both parties agreed to stipulate to the dismissal of the litigation without prejudice; and Schering received licenses to market five Upsher-Smith products.

45. The $60 million payment from Schering to Upsher-Smith was unrelated to the value of the products Upsher-Smith licensed to Schering.

46. The licensed products were of little value to Schering. Schering never sold four of the five licensed products, made minimal sales of the fifth, and has no expectation of making additional sales of any of the five products.

47. A court decision in the Schering patent infringement suit against Upsher-Smith would have removed barriers to generic competition, regardless of which party prevailed in the suit. If Upsher-Smith had prevailed, the FDA would have been permitted to grant final approval to Upsher-Smith's generic version of K-Dur 20, allowing Upsher-Smith to offer generic competition to Schering. After Upsher-Smith's 180-day Exclusivity Period had run, other potential generic competitors would have been eligible for final FDA approval. If Schering had prevailed, Upsher-Smith would not have been eligible for the 180-day Exclusivity Period. Since no other firm would have been eligible for the 180-day Exclusivity Period, there would have been no 180-day Exclusivity Period blocking final FDA approval of other generic competitors. Thus, the settlement agreement between Schering and Upsher-Smith preserved a barrier to generic competition to K-Dur 20.

48. In November 1998, Upsher-Smith received final FDA approval to market its Klor Con M20 generic version of Schering's K-Dur 20.

49. Pursuant to its agreement with Schering, Upsher-Smith has not marketed Klor Con M20, nor has it attempted to develop another generic version of Schering's K-Dur 20.

50. Under the Hatch-Waxman Act, the FDA is not permitted to grant final approval to a generic version of K-Dur 20, other than Upsher-Smith's Klor Con M20, until the 180-day Exclusivity Period has run.

Schering/AHP/ESI Agreement Not To Compete

51. On December 29, 1995, ESI submitted an ANDA to the FDA to market a generic version of Schering's K-Dur 20. ESI submitted a Paragraph IV Certification with this filing and notified Schering of its Paragraph IV Certification and ANDA filing.

52. ESI planned to launch its generic version of K-Dur 20 after Upsher-Smith's 180-day Exclusivity Period expired.

53. Schering sued ESI for patent infringement in the United States District Court for the Eastern District of Pennsylvania on February 16, 1996, alleging that ESI's generic version of Schering's K-Dur 20 infringed Schering's '743 patent. Schering's lawsuit triggered the statutory waiting period of up to 30 months for FDA approval of the ESI product.

54. By the end of January 1998, Schering, AHP, and ESI had reached an agreement in principle to settle their patent litigation.

55. Pursuant to their agreement in principle, Schering agreed to pay ESI up to $30 million; AHP and ESI agreed to refrain from marketing the allegedly infringing generic version of K-Dur 20 or with any other generic version of K-Dur 20, regardless of whether such

product would infringe Schering's patents, until January 2004; AHP and ESI agreed to refrain from marketing more than one generic version of K-Dur 20 between January 2004 and September 2006; and AHP and ESI agreed not to conduct, sponsor, file or support a study of the bioequivalence of any product to K-Dur 20 prior to September 2006, when the K-Dur 20 patent will expire. Schering agreed to pay ESI $5 million up front; an additional $10 million if ESI could demonstrate that its generic version of K-Dur 20 was able to be approved by the FDA under an ANDA on or before June 30, 1999; and another $15 million for licenses of two generic products that ESI was developing. The payments for the licenses included $5 million to be paid within ten days of execution of the agreement, plus $10 million to be paid in annual installments over seven years.

56. Schering has made no sales to date of the two products it licensed from ESI.

57. Instead of being based on the value of the licensed products, the $15 million license payment is based on the amount that ESI wanted in order to settle its patent litigation with Schering.

58. On June 19, 1998, Schering and ESI executed their final settlement agreement. Their patent litigation had previously been dismissed with prejudice.

59. Schering has paid ESI over $20 million and continues to make annual payments to ESI under the terms of their agreement.

60. ESI received tentative approval of its ANDA from the FDA on May 11, 1999, but is not eligible for final approval until Upsher-Smith's 180-day Exclusivity Period expires.

Other Potential Generic Competition

61. Andrx Corporation ("Andrx") filed an ANDA for a generic version of Schering's K-Dur 20 on June 2, 1999. Schering has not sued Andrx for infringement of the '743 patent.

62. Andrx cannot market its product until Upsher-Smith's 180-day Exclusivity Period has run.

Effects Of Respondents' Conduct

63. The acts and practices of the respondents as herein alleged have had the purpose and effect to restrain competition unreasonably and to injure competition by preventing or discouraging the entry of generic K-Dur 20 products into the relevant markets.

64. By making cash payments to Upsher-Smith and ESI, Schering induced them to agree to delay launching generic versions of K-Dur 20. Absent those payments, neither Upsher-

Smith nor ESI would have agreed to delay its entry for so long.

65. By making cash payments to Upsher-Smith and ESI, Schering protected itself from competition in the relevant markets from Upsher-Smith and ESI until 2001 and 2004, respectively.

66. Upsher-Smith's agreement with Schering not to compete with a generic version of K-Dur 20 until September 2001 has the effect of delaying entry into the relevant market by any other potential generic competitor. As the first ANDA filer for a generic version of K-Dur 20, Upsher-Smith is entitled to 180 days of market exclusivity before any other generic competitor may enter with its own generic version of K-Dur 20. By avoiding a court decision that would have either (a) triggered this 180-day Exclusivity Period (in the event Upsher-Smith prevailed) or (b) resulted in its forfeiture (in the event Schering prevailed), the challenged agreement delays the start of Upsher-Smith's 180-day Exclusivity Period until September 2001 and, as a result, the entry of competition from other generic manufacturers until March 2002.

67. As a result of respondents' conduct as herein alleged, consumers are being deprived of the benefits of competition from Upsher-Smith, ESI, or other generic competitors. Without this lower-priced generic competition, consumers, pharmacies, hospitals, insurers, wholesalers, government agencies, managed care organizations, and others are forced to purchase Schering's more expensive K-Dur 20 product.

First Violation Alleged

68. The agreement between Schering and Upsher-Smith that Upsher-Smith will not compete by marketing any generic version of Schering's K-Dur 20 until September 2001 unreasonably restrains commerce, and is therefore an unfair method of competition, in violation of Section 5 of the FTC Act.

Second Violation Alleged

69. The agreement between Schering, AHP, and ESI that ESI will not compete by marketing any generic version of Schering's K-Dur 20 until January 2004, market more than one generic version of Schering's K-Dur 20 between January 2004 and September 2006, or support any study of the bioequivalence or therapeutic equivalence of a product to K-Dur 20 until September 5, 2006, unreasonably restrains commerce, and is therefore an unfair method of competition, in violation of Section 5 of the FTC Act.

Third Violation Alleged

70. Schering has monopoly power in the manufacture and sale of potassium chloride supplements approved by the FDA and narrower markets contained therein, and engaged

in conduct intended to unlawfully preserve such monopoly power in violation of Section 5 of the FTC Act.

Fourth Violation Alleged

71. Schering conspired separately with Upsher-Smith and AHP that Schering monopolize the manufacture and sale of potassium chloride supplements approved by the FDA and narrower markets contained therein, and all three respondents acted with specific intent and engaged in overt acts in furtherance of these conspiracies to monopolize the relevant markets, in violation of Section 5 of the FTC Act.

NOTICE

Proceedings on the charges asserted against you in this complaint will be held before an Administrative Law Judge (ALJ) of the Federal Trade Commission, under Part 3 of the Commission's Rules of Practice, 16 C.F.R. Part 3. A copy of Part 3 of the Rules is enclosed with this complaint.

You may file an answer to this complaint. Any such answer must be filed within 20 days after service of the complaint on you. If you contest the complaint's allegations of fact, your answer must concisely state the facts constituting each ground of defense, and must specifically admit, deny, explain, or disclaim knowledge of each fact alleged in the complaint. You will be deemed to have admitted any allegations of the complaint that you do not so answer.

If you elect not to contest the allegations of fact set forth in the complaint, your answer shall state that you admit all of the material allegations to be true. Such an answer will constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the ALJ will file an initial decision containing appropriate findings and conclusions and an appropriate order disposing of the proceeding. Such an answer may, however, reserve the right to submit proposed findings and conclusions and the right to appeal the initial decision to the Commission under Section 3.52 of the Commission's Rules of Practice.

If you do not answer within the specified time, you waive your right to appear and contest the allegations of the complaint. The ALJ is then authorized, without further notice to you, to find that the facts are as alleged in the complaint and to enter an initial decision and a cease and desist order.

The ALJ will schedule an initial prehearing scheduling conference to be held not later than 7 days after the last answer is filed by any party named as a respondent in the complaint. Unless otherwise directed by the ALJ, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the prehearing scheduling conference, and Rule 3.31(b) obligates counsel for each party, within 5

days of receiving a respondent's answer, to make certain initial disclosures without awaiting a formal discovery request.

A hearing on the complaint will begin on July 2, 2001, at 10:00 A.M. in Room 532, or such other date as determined by the ALJ. At the hearing, you will have the right to contest the allegations of the complaint and to show cause why a cease and desist order should not be entered against you.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in an adjudicative proceeding in this matter that the respondents are in violation of Section 5 of the Federal Trade Commission Act, as alleged in the complaint, the Commission may order such relief as is supported by the record and is necessary and appropriate including, but not limited to, an order that requires the following:

1. Each respondent shall cease and desist from being a party to any settlement of patent infringement litigation which involves collateral restraints, such as a restraint on the research, development, manufacture, marketing, or sale of a "non-infringing" drug product – i.e., a drug product not at issue in the patent infringement litigation.

2. Each respondent shall cease and desist from being a party to any agreement in which one party agrees to refrain from conducting or assisting a study of the bioequivalence or therapeutic equivalence of a product to the NDA holder's drug product.

3. Each respondent shall cease and desist from being a party to any agreement in which the NDA holder provides anything of value to the alleged infringer and the alleged infringer agrees to refrain from selling a drug product for any period of time.

4. Schering shall immediately license for no compensation its '743 patent to Upsher-Smith and to ESI so as to allow the latter two companies to make, produce, and market commercially generic versions of Schering's K-Dur 20 and K-Dur 10. Said license must eliminate any and all legal claims that Schering would have for patent infringement by Upsher-Smith and ESI for selling the generic potassium chloride products for which each has already applied to the FDA for an ANDA.

5. Upsher-Smith shall immediately and without delay notify the FDA, in writing, that Upsher-Smith relinquishes its right to a 180-day Exclusivity Period for Klor Con M20 (its generic version of K-Dur 20).

6. Each respondent shall mail a copy of the Commission's complaint and order in this matter, along with a letter from such respondent's chief executive officer stating that it will abide by the terms of this order, to each of its employees who has the authority to enter into

agreements concerning the research, development, manufacture, marketing, or sale of a drug product.

7. Each respondent shall take such other measures as are appropriate to correct or remedy, or prevent the recurrence of, the anticompetitive practices engaged in by respondents.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this thirtieth day of March, 2001, issues its complaint against said respondents.

By the Commission.

Donald S. Clark
Secretary

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of

HOECHST MARION ROUSSEL, INC., a corporation,
CARDERM CAPITAL L.P., a limited partnership,

and

ANDRX CORPORATION, a corporation.

Docket No. 9293

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission ("Commission"), having reason to believe that respondents Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Corporation have engaged in conduct, as described herein, that violates Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows:

The Respondents

1. Respondent Hoechst Marion Roussel, Inc. ("Hoechst MRI") is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 10236 Marion Park Drive, Kansas City, Missouri. Hoechst MRI is, directly or indirectly, a wholly-owned subsidiary of Aventis, S.A., which is incorporated under the laws of the Republic of France with its office and principal place of business at 25 Quai Paul Doumier, 92408 Courbevoie Cedex, France. Hoechst MRI is engaged in the development, manufacture, distribution, and sale of pharmaceutical and health care products in the United States. Among other products, Hoechst MRI manufactures and sells Cardizem CD, a cardiovascular drug used to treat hypertension and angina.

2. At all relevant times herein, Hoechst MRI has been, and is now, a corporation as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

3. Respondent Carderm Capital L.P. ("Carderm") is a Delaware limited partnership having its office and principal place of business at Richmond House, 12 Par-la-Ville Road, Hamilton, Bermuda. Carderm is directly or indirectly owned or controlled by Hoechst MRI. Carderm holds the rights to three patents relating to Cardizem CD.

4. At all relevant times herein, Carderm has been, and is now, a partnership as "partnership" is used in Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

5. Respondent Andrx Corporation ("Andrx") is a corporation organized, existing, and

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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The Respondents

1. Respondent Hoechst Marion Roussel, Inc. ("Hoechst MRI") is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 10236 Marion Park Drive, Kansas City, Missouri. Hoechst MRI is, directly or indirectly, a wholly-owned subsidiary of Aventis, S.A., which is incorporated under the laws of the Republic of France with its office and principal place of business at 25 Quai Paul Doumier, 92408 Courbevoie Cedex, France. Hoechst MRI is engaged in the development, manufacture, distribution, and sale of pharmaceutical and health care products in the United States. Among other products, Hoechst MRI manufactures and sells Cardizem CD, a cardiovascular drug used to treat hypertension and angina.

2. At all relevant times herein, Hoechst MRI has been, and is now, a corporation as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

3. Respondent Carderm Capital L.P. ("Carderm") is a Delaware limited partnership having its office and principal place of business at Richmond House, 12 Par-la-Ville Road, Hamilton, Bermuda. Carderm is directly or indirectly owned or controlled by Hoechst MRI. Carderm holds the rights to three patents relating to Cardizem CD.

4. At all relevant times herein, Carderm has been, and is now, a partnership as "partnership" is used in Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

5. Respondent Andrx Corporation ("Andrx") is a corporation organized, existing, and

doing business under and by virtue of the laws of the State of Florida, with its office and principal place of business located at 4001 S.W. 47th Avenue, Fort Lauderdale, Florida, 33314. Andrx develops, manufactures, and markets controlled-release pharmaceutical products. Andrx developed a generic or bioequivalent version of Cardizem CD, which has been approved by the FDA for sale in the United States.

6. At all relevant times herein, Andrx has been, and is now, a corporation as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

7. Respondents' acts and practices, including the acts and practices alleged herein, are in or affect commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

Federal Regulation of Pharmaceutical Products

8. Under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., approval by the United States Food & Drug Administration ("FDA") is required before a company may market or sell a pharmaceutical product in the United States. Approval for a new or brand name drug is sought by filing a New Drug Application ("NDA") with the FDA.

9. A generic drug is a product that the FDA has found to be bioequivalent to a brand name drug. Generic drugs are chemically identical to their branded counterparts, but typically are sold at substantial discounts from the branded price. Approval may be sought for a generic version of a brand name drug by filing an Abbreviated New Drug Application ("ANDA") with the FDA.

10. The FDA maintains a book of Approved Drug Products With Therapeutic Evaluations (commonly known as the "FDA Orange Book"), which lists all patents that the brand name manufacturer asserts relate to each brand name drug. If an applicant intends to market a generic product prior to the expiration of one or more patents relating to a brand name drug, the applicant must certify to the FDA, when appropriate, that the patent or patents listed in the FDA Orange Book are either invalid or not infringed by the generic version of the product (a "Paragraph IV Certification"), and must notify the holder of the approved NDA and the owner of the patent or patents of the filing of the ANDA. If neither the patent holder nor the NDA holder files a patent infringement suit against the ANDA filer within 45 days of receipt of notification of a Paragraph IV Certification, the FDA review and approval process may proceed and, upon FDA approval of the ANDA, the generic product may be marketed. If a patent infringement suit is filed against the ANDA filer within the 45-day period, however, FDA approval of the ANDA is automatically stayed until the earliest of: (i) patent expiration; (ii) a final judicial determination of non-infringement or invalidity in a lawsuit; or (iii) the expiration of a 30-month period from the time the patent holder receives Paragraph IV Certification.

11. The Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355 (the "Hatch-Waxman Act"), as currently implemented by the FDA, provides that the first applicant to submit an ANDA with a Paragraph IV Certification for a generic version of a brand name drug ("ANDA First Filer") is entitled to a 180-day period of marketing exclusivity ("180-day Exclusivity Period") before the FDA may grant final approval of any other generic manufacturer's ANDA regarding the same brand name drug. This period does not begin to run until either the generic is commercially marketed

or a court enters final judgment that the patents subject to the Paragraph IV Certification are invalid or not infringed. No other generic manufacturer may obtain FDA approval to market its product until the ANDA First Filer's 180-day Exclusivity Period has expired.

Relevant Product And Geographic Market

12. A relevant product market for assessing respondents' anticompetitive conduct is once-a-day diltiazem. Diltiazem belongs to a group of drugs known as "calcium channel blockers," and is used principally to treat high blood pressure (hypertension) and to decrease the occurrence of chronic chest pain ("angina"). Once-a-day diltiazem is a time-release version of diltiazem, in capsule form, that is designed to be taken once every 24 hours. Other calcium channel blockers are not acceptable substitutes for diltiazem for several reasons, including, inter alia, the differences in efficacy and side effects, and the risks associated with switching patients from one calcium channel blocker to another. In addition, narrower relevant product markets may be contained within the market for once-a-day diltiazem products. Total U.S. sales of once-a-day diltiazem products amount to roughly $1 billion per year, with Hoechst MRI's U.S. sales of Cardizem CD, one of the brand name once-a-day diltiazem products, accounting for over $700 million per year.

13. The relevant geographic market is the United States.

Monopoly Power

14. At all relevant times herein, Hoechst MRI had monopoly power in the U.S. market for once-a-day diltiazem ("the relevant market"), and in narrower markets contained therein. Hoechst MRI distributes the leading once-a-day diltiazem drug, Cardizem CD, which, at all relevant times, accounted for over 70% of total sales in the relevant market.

15. At all relevant times herein, entry into the relevant market was restricted and unlikely to diminish Hoechst MRI's monopoly power. Before entry could occur, potential entrants were required to, inter alia, file an NDA or an ANDA with the FDA, and obtain FDA final approval. At all relevant times, the FDA did not have an NDA accepted for filing for a new once-a-day diltiazem drug. If a new NDA were to be filed with the FDA, final approval would likely take a minimum of 12-18 months. Furthermore, any new once-a-day diltiazem drug introduced pursuant to an NDA would be unlikely to have a significant impact on the market, unless the new drug were bioequivalent to Cardizem CD.

16. At all relevant times herein, FDA final approval of an ANDA for a generic version of Cardizem CD for anyone other than Andrx was blocked. Pursuant to the Hatch- Waxman Act, as interpreted by the FDA, Andrx held the right to a 180-day Exclusivity Period for the sale of a generic version of Cardizem CD. As a result, no company could obtain FDA final approval of an ANDA to market or sell a generic version of Cardizem CD until 180 days after Andrx first sold its product, or until Andrx relinquished or otherwise lost its exclusivity right. Other than Andrx, only two companies had submitted ANDAs for a generic version of Cardizem CD to the FDA: Purepac Pharmaceutical Co. ("Purepac"), a subsidiary of Faulding Inc., and Biovail Corporation International ("Biovail"). Purepac and Biovail did not receive final FDA approval until Andrx's 180-day Exclusivity Period expired in December 1999.

Factual Background

17. In or around September 1995, Andrx filed the first ANDA with the FDA for the manufacture and sale of a generic version of Cardizem CD. In December 1995, Andrx certified to the NDA holder of Cardizem CD that the product covered by its ANDA did not infringe any of the patents covering Cardizem CD. Pursuant to the Hatch-Waxman Act, as currently interpreted, this filing entitled Andrx to a 180-day period during which it would hold the exclusive right to market and sell a generic version of Cardizem CD.

18. On January 31, 1996, Hoechst MRI and Carderm filed a lawsuit against Andrx in the U.S. District Court for the Southern District of Florida, alleging infringement of a patent claiming Cardizem CD. Pursuant to the Hatch-Waxman Act, unless the lawsuit was resolved at an earlier date, this lawsuit triggered a 30-month stay of final FDA approval of Andrx's ANDA, until July 1998.

19. In January 1997, Purepac filed an ANDA with the FDA for the manufacture and sale of a generic version of Cardizem CD. On January 31, 1997, Hoechst MRI filed a lawsuit against Purepac in the U.S. District Court for the District of New Jersey, alleging patent infringement. Pursuant to the Hatch-Waxman Act, unless the lawsuit was resolved at an earlier date, this lawsuit triggered a 30-month stay of final FDA approval of Purepac's ANDA, until July 1999.

20. On or about June 19, 1997, Biovail filed an ANDA with the FDA for the manufacture and sale of a generic version of Cardizem CD. Hoechst AG, Hoechst MRI, and Biovail had previously entered into a General Release and Covenant Not to Sue with respect to any claim of patent infringement relating to formulations for a once-daily medicine containing diltiazem.

Anticompetitive Conduct

21. Despite the terms of the General Release and Covenant Not to Sue, representatives of Hoechst MRI met with Biovail in early August 1997, ostensibly to discuss resolution of a potential claim of Hoechst MRI against Biovail for patent infringement relating to Biovail's generic version of Cardizem CD, as well as to discuss development of a new indication or use for the drug Probucol, a product for which Hoechst MRI held an approved NDA but which was not then being marketed or sold. During the course of these meetings, Hoechst MRI offered to pay Biovail a substantial amount of money to complete testing and the FDA approval process for a new Probucol indication. This offer was contingent on Biovail's agreeing to refrain from entering the market with a bioequivalent or generic version of Cardizem CD until at least July 1999. Biovail rejected Hoechst MRI's proposal. Hoechst MRI did not sue Biovail for patent infringement with respect to Biovail's generic or bioequivalent Cardizem CD product.

22. Beginning in late July 1997, representatives of Hoechst MRI and Andrx engaged in discussions of a possible agreement in connection with Hoechst MRI's pending patent infringement lawsuit against Andrx, pursuant to which Andrx would agree to refrain from bringing a generic version of Cardizem CD to market for a specific period of time.

23. On September 24, 1997, Hoechst MRI, Carderm, and Andrx entered into a Stipulation and Agreement. The Stipulation and Agreement did not settle the lawsuit -- indeed, it specifically contemplated that the parties would continue the litigation to final judicial resolution. Instead, Hoechst MRI, Carderm, and Andrx agreed among themselves that

Andrx would not enter the market with the generic version of Cardizem CD covered by its ANDA until the earliest of (1) the entry of final judgment in the patent lawsuit, (2) Andrx's obtaining a license from Hoechst MRI under the terms and conditions specified in the Stipulation and Agreement, or (3) Hoechst MRI's providing notice that it intended to license a third party or sell its own bioequivalent or generic version of Cardizem CD. In the Stipulation and Agreement, Andrx also agreed - at Hoechst MRI's insistence - to refrain from selling any other bioequivalent or generic version of Cardizem CD, regardless of whether such product would infringe Hoechst MRI's or Carderm's patents. In addition, Andrx agreed not to withdraw its pending ANDA or to relinquish or otherwise compromise any right accruing under its ANDA, including its right to a 180-day Exclusivity Period, until the entry of final judgment in the patent lawsuit.

24. In exchange for Andrx's various agreements, Hoechst MRI agreed to pay Andrx $10 million per quarter, beginning upon final FDA approval of Andrx's ANDA (*i.e.*, once Andrx could otherwise have marketed) and continuing until the occurrence of either (1), (2) or (3) described above in Paragraph 23. The Stipulation and Agreement also provided that, should Hoechst MRI lose the patent infringement suit, Hoechst MRI would pay Andrx an additional $60 million per year for that same time period.

25. The Stipulation and Agreement further provided that, beginning January 9, 2000 or upon the earlier occurrence of any of certain specified events, Andrx would have an option to acquire a license to Hoechst MRI's intellectual property in Cardizem CD. The amount of the royalties to be paid by Andrx to Hoechst MRI would depend on the ultimate outcome of the patent litigation - *i.e.*, Andrx would pay a higher royalty if Andrx ultimately lost the patent infringement litigation.

26. In the event Andrx breached any of its obligations under the Stipulation and Agreement, it would be required to repay all amounts received. For example, if Andrx breached one of its obligations one year after receiving final FDA approval, it would be required to repay $40 million to Hoechst MRI. In addition, by its terms, the Stipulation and Agreement would terminate in the event of a breach by Andrx, thus extinguishing any right of Andrx to receive an additional payment should it prevail in the patent lawsuit, or to exercise a license should it lose the lawsuit.

27. On July 9, 1998, the FDA granted final approval for Andrx's ANDA for a generic version of Cardizem CD. This approval permitted Andrx to begin the marketing and sale of its generic version of Cardizem CD immediately. In accordance with the terms of the Stipulation and Agreement, Andrx did not begin commercial sale of its generic product. As a result, pursuant to the terms of the Stipulation and Agreement, Hoechst MRI began making quarterly payments of $10 million to Andrx.

28. On September 11, 1998, Andrx submitted a Supplemental ANDA to the FDA reflecting a modified formulation of its generic Cardizem CD product. Andrx filed a Paragraph IV Certification, stating its belief that Hoechst MRI had no legitimate basis to claim patent infringement by the product reflected in the Supplemental ANDA. Andrx's Supplemental ANDA received FDA approval on June 8, 1999. On or around that same day, Andrx and HMRI entered into a second agreement, essentially abrogating the Stipulation and Agreement and clearing the way for Andrx to go to market. Andrx began marketing a generic version of Cardizem CD on or around June 23, 1999.

The Effects of Respondents' Conduct

29. The acts and practices of the respondents as herein alleged have had the purpose or effect, or the tendency or capacity, to restrain competition unreasonably and to injure competition and consumers by preventing or discouraging the entry of competition in the form of generic versions of Cardizem CD into the relevant market.

30. Earlier entry of a generic version of Cardizem CD would have had a significant procompetitive impact in the relevant market. Pharmacists generally are permitted, and in some instances required, to substitute FDA-recognized generic drugs for their branded counterparts, without obtaining the prescribing physician's approval. In addition, there is a ready market for generic products because certain third-party payers of prescription drugs (*e.g.*, managed care plans and Medicaid programs) encourage or insist on the use of generic drugs wherever possible. A generic product can quicky and efficiently enter the marketplace at substantial discounts, generally leading to a significant erosion of the branded drug's sales within the first year. For example, respondents' forecasts projected that a generic version of Cardizem CD, sold at 70% of the brand price, would capture roughly 40% of Cardizem CD sales within the first year.

31. The purpose and intended effect of the $10 million quarterly payments from Hoechst MRI to Andrx during the term of the Stipulation and Agreement was to provide an incentive for Andrx to refrain both from entering the relevant market, and from taking any steps, including relinquishing its right to a 180-day Exclusivity Period, to permit or facilitate the entry of any other generic manufacturer.

32. By prohibiting Andrx from commencing the commercial sale not only of the product subject to the patent infringement suit, but also of any bioequivalent or generic version of Cardizem CD during the term of the agreement, the Stipulation and Agreement had the purpose and intended effect of deterring Andrx from selling any non-infringing or potentially non-infringing version of its generic Cardizem CD product. As a result, the Stipulation and Agreement was intended to have the effect of delaying substantially Andrx's entry into the relevant market with a generic version of Cardizem CD.

33. By prohibiting Andrx from withdrawing its pending ANDA or relinquishing or otherwise compromising any right accruing under its ANDA, including its right to a 180-day Exclusivity Period, until the entry of final judgment in the patent lawsuit, the Stipulation and Agreement had the purpose or effect of deterring Andrx from relinquishing its eligibility for a 180-day Exclusivity Period under the Hatch-Waxman Act. As a result, the Stipulation and Agreement was intended to have the effect of delaying substantially the entry into the relevant market of generic versions of Cardizem CD produced by other manufacturers.

34. The Stipulation and Agreement is not justified by any countervailing efficiencies.

35. Although the Stipulation and Agreement provided Andrx with the option of selling a generic version of Cardizem CD pursuant to a license from Hoechst MRI at a future date, this did not offset the anticompetitive effects set forth above. Entry by Andrx pursuant to the license was likely to occur, if at all, at a later date than would entry by Andrx or another generic manufacturer in the absence of the Stipulation and Agreement. In addition, the license required payment of substantial license fees, subject to the possibility of repayment if Andrx ultimately prevailed in the patent infringement suit. The requirement to pay substantial license fees may have reduced Andrx's incentive to exercise the licensing option. Moreover, entry by Andrx subject to the payment of

substantial license fees, even if they may ultimately have been reimbursable, was likely to be competitively less significant than entry without the requirement to pay such fees.

Violations Alleged

36. The Stipulation and Agreement among Hoechst MRI, Carderm and Andrx as a whole, and in particular the specific provisions described in Paragraphs 32 and 33 above, constitute unreasonable restraints of trade in violation of Section 5 of the Federal Trade Commission Act, as amended.

37. Hoechst MRI had the specific intent to preserve its monopoly in the relevant market and narrower markets contained therein, and its actions - including proposing, negotiating and entering into the Stipulation and Agreement among Hoechst MRI, Carderm, and Andrx, and proposing a similar agreement with Biovail - created a dangerous probability that it would accomplish its monopolistic objectives, in violation of Section 5 of the Federal Trade Commission Act, as amended.

38. Hoechst MRI, Carderm, and Andrx acted with the specific intent that Hoechst MRI monopolize the relevant market, and engaged in overt acts described in Paragraphs 21-28 above in furtherance of a conspiracy to monopolize the relevant markets, in violation of Section 5 of the Federal Trade Commission Act, as amended.

39. The acts and practices described above are anticompetitive in nature and tendency and constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, as amended.

NOTICE

Proceedings on the charges asserted against you in this complaint will be held before an Administrative Law Judge (ALJ) of the Federal Trade Commission, under Part 3 of the Commission's Rules of Practice, 16 C.F.R. Part 3. A copy of Part 3 of the Rules is enclosed with this complaint.

You may file an answer to this complaint. Any such answer must be filed within 20 days after service of the complaint on you. If you contest the complaint's allegations of fact, your answer must concisely state the facts constituting each ground of defense, and must specifically admit, deny, explain, or disclaim knowledge of each fact alleged in the complaint. You will be deemed to have admitted any allegations of the complaint that you do not so answer.

If you elect not to contest the allegations of fact set forth in the complaint, your answer shall state that you admit all of the material allegations to be true. Such an answer will constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the ALJ will file an initial decision containing appropriate findings and conclusions and an appropriate order disposing of the proceeding. Such an answer may, however, reserve the right to submit proposed findings and conclusions and the right to appeal the initial decision to the Commission under Section 3.52 of the Commission's Rules of Practice.

If you do not answer within the specified time, you waive your right to appear and contest

the allegations of the complaint. The ALJ is then authorized, without further notice to you to find that the facts are as alleged in the complaint and to enter an initial decision and a cease and desist order.

The ALJ will schedule an initial prehearing scheduling conference to be held not later than 7 days after the last answer is filed by any party named as a respondent in the complaint. Unless otherwise directed by the ALJ, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the prehearing scheduling conference, and Rule 3.31(b) obligates counsel for each party, within 5 days of receiving a respondent's answer, to make certain initial disclosures without awaiting a formal discovery request.

A hearing on the complaint will begin on November 14, 2000 at 10:00 A.M. in Room 532, or such other date as determined by the ALJ. At the hearing, you will have the right to contest the allegations of the complaint and to show cause why a cease and desist order should not be entered against you.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in an adjudicative proceeding in this matter that the respondents are in violation of Section 5 of the Federal Trade Commission Act, as alleged in the complaint, the Commission may order such relief as is supported by the record and is necessary and appropriate including, but not limited to, an order that requires the following:

1. Each Respondent shall cease and desist, either directly or indirectly, in connection with the sale of Drug Products in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, from being a party to any Agreement in which one party is an NDA holder for a Drug Product(s), any other party is the ANDA First Filer for the Drug Product(s), and:

   A. the ANDA First Filer is prohibited by such Agreement from relinquishing, or is subject to a penalty, forfeiture, or loss of benefit if it relinquishes, its right to the 180-Day Exclusivity Period; or

   B. the ANDA First Filer agrees to refrain from researching, developing, manufacturing, marketing, or selling any Drug Product that could be approved for sale by the FDA pursuant to the ANDA and that is not the subject of a court action alleging patent infringement.

Provided, however, that nothing in this Section shall prohibit Agreements involving the complete transfer of rights in a Drug Product.

2. In any instance where any Respondent is a party to a patent infringement action in which it is either the NDA Holder or the alleged infringer, it shall cease and desist, either directly or indirectly, in connection with the sale of Drug Products in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, from being a party to any Agreement in which the parties do not agree to dismiss the litigation, and in which the NDA Holder provides anything of value to the alleged infringer and the alleged infringer agrees to refrain

during part or all of the course of the litigation from selling the Drug Product at issue, or any Drug Product containing the same chemical entity(ies) at issue. *Notwithstanding the above, however*, such an Agreement is permissible when entered into in conjunction with a joint stipulation between the parties that the court may enter a preliminary injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure, if: (1) together with the stipulation for a preliminary injunction, the Respondent provides the court with the proposed Agreement, as well as a copy of the Commission's complaint, order, and Analysis to Aid Public Comment in this matter; (2) the Respondent has provided Notification, as described in Paragraph 4 below, to the Commission at least thirty (30) days prior to submitting the stipulation for a preliminary injunction; (3) the Respondent does not oppose any effort by the Commission to participate, in any capacity permitted by the court, in the court's consideration of any such action for preliminary relief; and (4) the court issues an order which incorporates the terms of the Agreement. Nothing in this Paragraph shall be interpreted to prohibit or restrict the right of any Respondent to unilaterally seek relief from the court, without notice to the Commission, including, but not limited to, applying for preliminary injunctive relief or seeking to extend the 30 month stay pursuant to 21 U.S.C. § 355(j)(4)(B)(iii).

3. Each Respondent shall provide Notification as described in paragraph 4 below to the Commission at least thirty (30) days before becoming a party to any Agreement whereby an ANDA First Filer agrees with an NDA holder to refrain from selling any Drug Product under its ANDA for any period of time.

4. The Prior Notification required by Paragraphs 2 and 3 shall be filed with the Secretary of the Commission and shall include the following information, to the extent known, and not subject to any legally recognized privilege: (1) identification of the parties involved in the Agreement; (2) identification of all Drug Products involved in the Agreement; (3) identification of all persons who have filed an ANDA with the FDA (including the status of such application) for any Drug Product containing the same chemical entity(ies) as the Drug Product(s) involved in the Agreement; (4) a copy of the proposed Agreement; (5) identification of the court, and a copy of the docket sheet, for any legal action which involves either party to the Agreement and relates to any Drug Product(s) containing the same chemical entity(ies) involved in the Agreement; and (6) all documents which were prepared by or for any officer(s) or director(s) of any Respondent for the purpose of evaluating or analyzing the Agreement.

5. Each Respondent shall mail a copy of the Commission's complaint and order in this matter, along with a letter from such Respondent's chief executive officer stating that it will abide by the terms of this order, to each of its employees who has the authority to enter into agreements concerning the research, development, manufacture, marketing, or sale of a Drug Product.

6. Each Respondent shall take such other measures as are appropriate to correct or remedy, or prevent the recurrence of, the anticompetitive practices engaged in by Respondents.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission, on this sixteenth day of March, 2000, issues its complaint against said Respondents.

By the Commission.

Donald S. Clark
Secretary

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	Docket No. 9293
Hoechst Marion Roussel, Inc., et al.,	)	
	)	
Respondents	)	
	)	

AVENTIS PHARMACEUTICALS, INC.
SUBPOENA DUCES TECUM TO THE
FOOD AND DRUG ADMINISTRATION

Respondent Aventis Pharmaceuticals, Inc, formerly known as Hoechst Marion Roussel, Inc., pursuant to the Federal Trade Commission's Rules of Practice for Adjudicative Proceedings, 16 C.F.R. § 3.36, requests that the U.S. Food and Drug Administration (hereinafter referred to as "FDA") produce documents and other things for inspection and copying, within 20 days, in response to the Document Requests set forth below, and in accordance with the Definitions and Instructions following thereafter, at the offices of Shook, Hardy & Bacon, L.L.P., 600 14th Street, N.W., Washington, D.C. 20005, or such location as may be mutually agreed upon.

DOCUMENTS REQUESTS

Request No. 1: All documents concerning any ANDA and NDA submitted by Biovail for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD, excluding the ANDA and NDA themselves. This request includes, by way of example, but is not limited to:

(a) all communications between the FDA and Biovail;

(b) all communications between the FDA and any person, including but not limited to any reports from and correspondence with external consultants, relating to the issues raised in the Andrx citizen petition; and

(c) all FDA analyses and communications, including but not limited to bioequivalence issues raised in the review of any ANDA and NDA submitted by Biovail for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD and documentation reflecting medical review of clinical studies contained in any NDA submitted by Biovail for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD.

Request No. 2: All documents concerning comments submitted to FDA by the FTC relating to FDA's proposed rule on 180-day generic drug exclusivity for ANDAs, including but not limited to any communication between the FDA and the FTC or any other person, and internal FDA communications.

Request No. 3: All documents which reflect the date of submission, filing, tentative approval and final approval of the ANDA submitted by Faulding for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD, excluding the ANDA itself.

Request No. 4: All documents which reflect the date of submission, filing, tentative approval and final approval of Andrx's ANDA for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD and any supplement thereto, excluding the ANDA and supplement themselves.

Request No. 5: All documents concerning development of Probucol for prevention of restenosis after coronary angioplasty, including but not limited to communications between the FDA and any person and any analysis, other evaluation or test regarding such development.

DEFINITIONS AND INSTRUCTIONS

1. As used herein, the term"Biovail" means Biovail Corporation International and any of its parents, subsidiaries, affiliates, divisions, employees, officers, directors, agents, lawyers, representatives, predecessors or successors. The term "Biovail" specifically includes Biovail's outside counsel, Cleary Gottlieb Steen & Hamilton.

2. As used herein, the term"Faulding" means Faulding, Inc. and any of its parents, subsidiaries, affiliates, divisions, employees, officers, directors, agents, lawyers, representatives, predecessors or successors.

3. As used herein, the term"Andrx" means Andrx Corporation, and any of its parents, subsidiaries, affiliates, divisions, employees, officers, directors, agents, representatives, predecessors or successors.

4. As used herein, the term"FDA" means the Federal Food and Drug Administration and its divisions, agents, representatives, predecessors or successors.

5. As used herein, the term"NDA" means a New Drug Application submitted to the FDA for approval for the manufacture and marketing of a pharmaceutical product.

6. As used herein, the term"ANDA" means an Abbreviated New Drug Application submitted to the FDA for approval for the manufacture and marketing of a pharmaceutical product that is the "bioequivalent" of an FDA approved, brand name pharmaceutical product.

7. As used herein, the term"FTC" means the Federal Trade Commission and its divisions, agents, representatives, predecessors or successors.

8. As used herein, the term"Andrx citizen petition" shall refer to FDA Docket No. 98P-0145.

9. As used herein, the term"FDA's proposed rule on 180-day generic drug exclusivity for ANDAs" shall refer to the rule published at 64 Fed. Reg. 42873 (Aug. 6, 1999) and identified by FDA Docket No. 85N-0214.

10. As used herein, the term s "document" or "documents" or "documentation" include these terms as defined by 16 C.F.R. § 3.34(b) and, in addition, the original or drafts or any kind of written, printed, recorded or graphic matter or sound reproduction, however produced or reproduced, whether sent or received or neither, and all copies thereof which are different in any way from the original (whether by notation, indication of copies sent or received or otherwise) regardless of whether designated "Confidential," "Privileged" or otherwise and including, but not limited to, any correspondence, paper, book, account, drawing, agreement, contract, e-mail, handwritten notes, invoice, memorandum, telegram, object, opinion, purchase order, report, records, transcript, summary, study, survey recording of any telephone or other conversation, interviews or notes of any conference. The terms "document" or "documents" shall also include data stored, maintained or organized electronically or magnetically or through computer equipment, translated, if necessary, by you into reasonably usable form, and film impressions, magnetic tape and sound or mechanical productions of any kind or nature whatsoever.

11. As used herein, the term "person" shall refer to any natural persons, firm, company, syndicate, group, pool, joint venture, partnership, trust, estate, corporation, or other form or organization or legal entity.

12. As used herein, the term"concern" and "concerning" mean relating to, referring to, describing, evidencing, or constituting.

13. As used herein, the terms "and" and "or" include both the conjunctive and disjunctive, as necessary, to bring within the scope of this request all responses that might otherwise be construed to be outside of its scope.

14. As used herein, the terms "any" "all" and "each" each shall be construed to mean "any, all and each".

15. The use of a singular form of any word includes the plural, and vice-versa.

16. The terms "include" and "including" are used for illustration and not by way of limitation.

17. Except for privileged materials, produce each responsive document in its entirety by including all attachments and all pages, regardless of whether they directly relate to the specified subject matter. Submit any appendix, table, or other attachment by either physically attaching it to the responsive document or clearly marking it to indicate the responsive document to which it corresponds. Except for privileged material, do not mask, cut, expunge, edit, or delete any responsive document or portion thereof in any manner.

18. If any documents that are responsive to the document requests herein are withheld from production, furnish a list of all such documents withheld. Said list shall contain a complete description of each document, including: (i) the type, date, and number of pages of the document; (ii) its title (if any); (iii) a general description of its subject matter; (iv) the identity of any attachments or appendices to the document; (v) the name and identification of each person to whom it is addressed; (vi) the name and identification of each person who received a copy thereof; (vii) the name and identification of the persons or person by whom it was written or

generated; (viii) its present custodian; (ix) the ground or grounds upon which it is being withheld.

19. In the event that any document called for by this document request has been destroyed or discarded, please identify each such document by stating: (i) any addresser and addressee; (ii) the addressees of any indicated or blind copies; (iii) the type, date, subject matter and number of pages of the document; (iv) a description of any attachment or appendices to the document; (v) the names and identification of all persons to whom the document was distributed, shown or explained; (vi) the date when it was destroyed or discarded, and the manner in which it was destroyed or discarded; and (vii) the names and identification of the persons authorizing and carrying out such destruction or discarding.

20. Unless otherwise indicated, this subpoena calls for the production of documents that were created or utilized during, or otherwise concern, the period from January 1993 through and including the date of production.

Dated: August 9, 2000

James M. Spears
Paul S. Schleifman
D. Edward Wilson, Jr.
Peter D. Bernstein
SHOOK HARDY & BACON, LLP
600 Fourteenth Street, N.W., Suite 800
Washington, D.C. 20005-2004
(202) 783-8400

Attorneys for Respondent
Aventis Pharmaceuticals, Inc.

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600 Fourteenth Street, N.W., Suite 800
Washington, D.C. 20005-2004
(202) 783-8400

Attorneys for Respondent
Aventis Pharmaceuticals, Inc.

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO

United States Food & Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

2. FROM

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

This subpoena requires you to produce and permit inspection and copying of designated books, documents (as defined in Rule 3.34(b)), or tangible things - or to permit inspection of premises - at the date and time specified in Item 5, at the request of Counsel listed in Item 9, in the proceeding described in Item 6.

3. PLACE OF PRODUCTION OR INSPECTION

Shook, Hardy & Bacon, L.L.P.
600 14th Street, N.W.
Suite 800
Washington, D.C. 20005

4. MATERIAL WILL BE PRODUCED TO

Solomon, Zauderer, Ellenhorn, Frischer & Sharp
Counsel for Respondent Andrx Corporation

5. DATE AND TIME OF PRODUCTION OR INSPECTION

July 31, 2000
10:00 a.m.

6. SUBJECT OF PROCEEDING

In the matter of Hoechst Marion Roussel, Inc., et al.

7. MATERIAL TO BE PRODUCED

See Exhibit A

8. ADMINISTRATIVE LAW JUDGE

The Honorable D. Michael Chappell

Federal Trade Commission
Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

Solomon, Zauderer, Ellenhorn, Frischer & Sharp
45 Rockefeller Plaza, 7th Floor
New York, New York 10111

Attorneys for Respondent Andrx

DATE ISSUED

JUN 29 2000

SECRETARY'S SIGNATURE

Donald S. Clark

GENERAL INSTRUCTIONS

APPEARANCE

The delivery of this subpoena to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply.

MOTION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any motion to limit or quash this subpoena be filed within the earlier of 10 days after service or the time for compliance. The original and ten copies of the petition must be filed with the Secretary of the Federal Trade Commission, accompanied by an affidavit of service of the document upon counsel listed in Item 9, and upon all other parties prescribed by the Rules of Practice.

TRAVEL EXPENSES

The Commission's Rules of Practice require that fees and mileage be paid by the party that requested your appearance. You should present your claim to counsel listed in Item 9 for payment. If you are permanently or temporarily living somewhere other than the address on this subpoena and it would require excessive travel for you to appear, you must get prior approval from counsel listed in Item 9.

This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

EXHIBIT "A"

Documents Requested

1. All documents concerning any ANDA and NDA submitted by Biovail for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD, excluding the ANDA and NDA themselves. This request includes, by way of example, but is not limited to:

    a) All communications between the FDA and Biovail; and

    b) All communications between the FDA and any third party; and

    c) All responsive internal FDA documents.

2. All documents concerning the ANDA submitted by Faulding for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD, excluding the ANDA itself. This request includes, by way of example, but is not limited to:

    a) All communications between the FDA and Faulding.

    b) All communications between the FDA and any third party; and

    c) All responsive internal FDA documents.

3) All communications between the FDA and any other party (excluding Andrx) concerning Andrx's ANDA for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD. This request includes, by way of example, but is not limited to:

    a) All communications between the FDA and the FTC concerning Andrx's ANDA; and

b) All documents concerning the FDA's decision to grant approval for Andrx's ANDA, including Andrx's reformulated product approved by the FDA on June 9, 1999 .

Definitions and Instructions

a. "Andrx" means Andrx Corporation, and any of its parents, subsidiaries, affiliates, divisions, employees, officers, directors, agents, representatives, predecessors or successors.

b. "Biovail" means Biovail Corporation International and any of its parents, subsidiaries, affiliates, divisions, employees, officers, directors, agents, lawyers, representatives, predecessors or successors. The term "Biovail" specifically includes Biovail's outside counsel, Cleary Gottlieb Steen & Hamilton.

c. "Faulding" means Faulding, Inc. and any of its parents, subsidiaries, affiliates, divisions, employees, officers, directors, agents, lawyers, representatives, predecessors or successors.

d. "FDA" means the Federal Food and Drug Administration and its divisions, agents, representatives, predecessors or successors.

e. "FTC" means the Federal Trade Commission, and its divisions (including its enforcement divisions), bureaus (including its Bureau of Competition), agents, representatives, predecessors or successors

f. "NDA" means a New Drug Application submitted to the FDA for approval for the manufacture and marketing of a pharmaceutical product.

g. "ANDA" means an Abbreviated New Drug Application submitted to the FDA for approval for the manufacture and marketing of a

pharmaceutical product that is the "bioequivalent" of an FDA approved, brand name pharmaceutical product.

h. The terms "document" and "documents" are used in their broadest sense, to the full extent permitted by the Federal Rules of Civil Procedure to mean , without limitation, any original written, recorded, filmed, or graphic matter of every type and description, whether produced or reproduced on paper, cards, tapes, film, electronic facsimile, computer storage disks, tapes, or devices, or any other media, and each copy of such writing, record, film, or graphic matter that is different in any way from the original or where such copy contains any commentary or notation whatsoever that does not appear on the original whether by interlineation, receipt stamp notation, inclusion of comments or notations, or otherwise and drafts. Documents specifically include, by way of illustration, but not by way of limitation, all letters, notes, diaries, E-mails, reports, studies, charts, graphs, memoranda, instruments, minutes, ledgers, records, recordings, tapes, microfilm, photographs, correspondence, telegrams, diaries, bookkeeping entries, financial statements, tax returns, checks, check stubs, notebook statements, affidavits, agreements, applications, books, pamphlets, periodicals, appointment calendars and work papers.

i. "Concern" and "concerning" mean relating to, referring to, describing, evidencing, or constituting.

j. The terms "and" and "or" include both the conjunctive and disjunctive, as necessary, to bring within the scope of this request all responses that might otherwise be construed to be outside of its scope.

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destroyed or discarded; and (vii) the names and identification of the persons authorizing and carrying out such destruction or discarding.

p. Unless otherwise indicated, this subpoena calls for the production of documents that were created or utilized during, or otherwise concern, the period from January, 1993 through and including the date of production.

q. This subpoena should be construed as not calling for the production of any documents prepared, authored, created, submitted or filed by Andrx.